

C2
26. (amended) An oral composition to treat migraine pain comprising pseudoephedrine, acetaminophen, and one or more pharmaceutically acceptable additives selected from the group consisting of a glidant, a lubricant, a disintegrating agent, a filler, and a pigmenting material.

Remarks

Claims 16, 18, 20, 22 and 26 are pending in the application. The Examiner has indicated claims 18, 20 and 22 are allowed.

Objection to claim because of informalities

The Examiner has objected to claim 26 because of the misspelling of "migraine" as "migrain". Applicant has amended the claim accordingly.

Rejection of claims under 35 U.S.C. § 112

The Examiner has rejected claim 26 under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is in particular to the phrase "an oral composition to treat migraine pain and other associated symptoms comprising a medicament component consisting of ..." (Examiner's emphasis) which the Examiner indicates renders the claim indefinite. Applicants have accordingly amended the claim to delete "a medicament component consisting of".

Rejection of claims under 35 U.S.C. § 103(a)

The Examiner has rejected claims 16 and 26 under 35 U.S.C. § 103(a) as being unpatentable over Armellino et al., U.S. Patent No. 5,972,916, ("Armellino et al.") in view of Munari et al. as explained by Applicant's specification, page 12, lines 9-23.

The Examiner states in paragraph five of the Office Action that Armellino et al. teach a method and composition for treating migraine headaches and associated symptoms, i.e. nausea, phonophobia, photophobia, pain and functional disability (Examiner's emphasis; see page 4, paragraph five of the Office Action). The Examiner also points out that Armellino et al. do not disclose a method or composition for treating migraines and the associated symptom of "functional disability" where the method includes administration of a composition additionally

containing pseudoephedrine (Examiner's emphasis; see page 5 of the Office Action, lines 3-4). The Examiner refers to the Munari et. al. reference which describes a study in which pseudoephedrine was administered to migraine patients and the resulting data demonstrated an effect on cardiovascular abnormalities. The Examiner indicates it would have been obvious to one of ordinary skill in the art to modify the method and composition of Armellino et al. by combining pseudoephedrine with the acetaminophen-containing compositions of Armellino et al. because one of ordinary skill in the art would reasonably expect the additive effect of the acetaminophen-containing compositions and the pseudoephedrine to be effective in treating migraine pain and functional disability associated therewith. The Examiner suggests moreover that one of ordinary skill in the art would reasonably expect pseudoephedrine to treat any cardiovascular abnormalities, i.e. a "functional disability", that the patients of Armellino may experience.

Applicant disagrees that the teaching of Munari et al. renders it obvious to one of ordinary skill in the art that pseudoephedrine would be reasonably expected to treat any cardiovascular abnormality associated with migraine. Munari et al. have only shown a limited set of cardiovascular responses to a limited set of autonomic tests in migraine sufferers who were in fact not suffering from migraine during the administration of the tests described by Munari et al.. Applicant has nonetheless amended claims 16 and 26 to cancel the "functional disability" language from claim 16 and "and other associated symptoms" from claim 26, thus relieving the Examiner from having to consider the relevance of the teaching of Munari et al. as it relates to the effects of pseudoephedrine on functional disability or other associated symptoms of migraine. Applicant believes claims 16 and 26 are accordingly non-obvious to one having ordinary skill in the art.

The Examiner also suggests Munari et al. establish that pseudoephedrine's efficacy is dependent on dosage amounts. Applicant respectfully points out that Munari et al. use pseudoephedrine at a constant relative concentration in each individual tested (see page 375 of Munari et al.) and further, not in combination with any other compounds. Therefore, Munari et al. do not teach or suggest in any way that pseudoephedrine efficacy is dependent on dosage amounts when used in combination with other drugs because its use in combination with other

drugs was not even investigated, nor does the Munari et al. reference teach or even suggest what the dosage amount appropriate for relieving migraine symptoms should be.

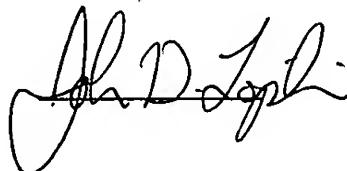
Conclusion

In view of the above arguments, Applicant believes that claims 16 and 26 are now in condition for allowance and therefore respectfully request the Examiner to withdraw the rejections and allow these claims. If a discussion with Applicant's attorney will facilitate the allowance of this application, Examiner Delacroix Muirhei is respectfully requested to call the undersigned at 716-848-1430.

Clean and marked up versions of the claims are enclosed herein.

A one-month extension is requested for filing this response. A check for \$55.00 is also enclosed. If any additional fee is due, the Examiner is authorized to charge it to Deposit Account No. 08-2442.

Respectfully submitted,



John D. Lopinski, Ph.D.
Reg. No. 50,846

Hodgson, Russ LLP
One M&T Plaza, Suite 2000
Buffalo, New York 14203
(716) 848-1628
March 20, 2003

Clean Copy of Amended Claims

16. A method of aborting a migraine attack, wherein the migraine attack is characterized by symptoms including nausea, photophobia and phonophobia, comprising the steps of administering to a human subject during a prodrome phase of the migraine attack a migraine abortive effective amount of a composition comprising a combination of pseudoephedrine and acetaminophen.

26. An oral composition to treat migraine pain comprising pseudoephedrine, acetaminophen, and one or more pharmaceutically acceptable additives selected from the group consisting of a glidant, a lubricant, a disintegrating agent, a filler, and a pigmenting material.

Marked-up copy of amended claims

16. A method of aborting a migraine attack, wherein the migraine attack is characterized by symptoms including nausea, photophobia[,] and phonophobia, [and/or functional disability,] comprising the steps of administering to a human subject during a prodrome phase of the migraine attack a migraine abortive effective amount of a composition comprising a combination of pseudoephedrine and acetaminophen.

26. An oral composition to treat migraine pain [and other associated symptoms] comprising [a medicament component consisting of] pseudoephedrine, acetaminophen, and one or more pharmaceutically acceptable additives selected from the group consisting of a glidant, a lubricant, a disintegrating agent, a filler, and a pigmenting material.